UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
THIS DOCUMENT RELATES TO: *State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al.*, Civil Action No. 03-11226-PBS	**Hon. Patti B. Saris**

DEFENDANTS' JOINT BRIEF IN SUPPORT OF
THEIR MOTIONS FOR PARTIAL SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

In this case, California seeks to recover over half a billion dollars from three drug manufacturers: Dey, Inc. and Dey, L.P. (collectively "Dey"), Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively "Mylan"), and Sandoz Inc. ("Sandoz")[1] under the California False Claims Act, Cal. Gov't Code § 12650 *et seq.* ("CFCA"). California alleges that Defendants caused to be published in third-party pricing compendia Average Wholesale Prices ("AWPs") that were higher than the average net prices paid by pharmacists and other providers in California's Medi-Cal program which in turn caused California, which used AWP as one of several bases to calculate reimbursements to providers, to pay providers more than their actual costs for the drugs. However, it is undisputed that California used the published AWPs with full knowledge that they did not reflect Medi-Cal providers' actual acquisition costs for Defendants' drugs because California had access to actual market prices for Defendants' drugs. Rather than being deceived, California deliberately chose to pay reimbursements based on published AWPs to meet its own policy goals and comply with the law in the Ninth Circuit.

Defendants move jointly here on two limited issues. ***First,*** California has not suffered and cannot claim damages since the Ninth Circuit issued its decision in *Orthopaedic Hospital* in January of 1997, which required California to perform studies to ensure that its Medicaid payments were consistent with the goals of economy, efficiency, quality service and access. In fact, the evidence in the record demonstrates as a matter of law that, since January of 1997, the reimbursement payments at issue were not "overpayments" at all, but were rather at a level that California consciously determined was sufficient to ensure that Medi-Cal beneficiaries had adequate access to quality care. Thus, California could not have been injured as a result of these

[1] Dey, Mylan, and Sandoz shall be referred to hereinafter collectively as "Defendants".

payments and consequently is not entitled to damages under the CFCA. Accordingly, California cannot show that Defendants' conduct after January 1997 caused it any injury.

Second, Defendants cannot be liable for any alleged wrongdoing after California received reports prepared by the accounting firm Myers and Stauffer in August of 2002 that examined California pharmacists' cost for both acquiring drugs and dispensing them to Medi-Cal beneficiaries. These reports confirmed what California had long understood, namely that for generic drugs as a class (as well as for many of the specific drugs at issue in this action), there existed large spreads (so-called "mega-spreads") between published AWPs and providers' acquisition costs. Moreover, the existence of these spreads for the drugs at issue in this action (the "Subject Drugs") was explicitly made clear to California by the relator, Ven-A-Care of the Florida Keys, Inc (the "Relator") in its amended *qui tam* complaint in this action filed in August of 2002. As the evidence demonstrates, California's decision to continue using AWP as a basis for reimbursement after August of 2002 was an informed policy decision and not the result of any deceptive conduct by Defendants.

Third, Defendants cannot be liable for damages for any claims paid on the basis of a FUL. The FULs set by CMS bore no rational, predictable relationship to Defendants' price reporting practices. In any event, California cannot demonstrate that it would have paid any less than the FULs if Defendants' reported prices were lower.

STATEMENT OF FACTS

I. CALIFORNIA'S INFORMED POLICY DECISIONS TO USE AWP IN DETERMINING MEDI-CAL PHARMACY REIMBURSEMENT

Beginning well before the commencement of this lawsuit, California understood that AWPs for drugs published in pricing compendia such as First DataBank, Medi-Span, and Red Book did not reflect net prices paid for drugs in the marketplace. Furthermore, California fully

understood that by using AWP in its reimbursement methodology, it paid Medi-Cal providers more – sometimes substantially more – than their actual acquisition costs for drugs. Nonetheless, California made specific policy decisions to maintain this reimbursement methodology.

In 1977, the California Department of Finance issued a report entitled "Medi-Cal Drug Price Controls, A Staff Reference Report," which documented cost-control measures under consideration for the Medi-Cal drug benefit. Defendants' Common Local Rule 56.1 Statement of Undisputed Material Facts ("SOF") at ¶ 23. The report recognized that pharmacies could purchase drugs at discounts from AWP that ranged from eight percent to 25 percent or more. *Id*. The report noted that, because Medi-Cal's reimbursement payments at the time were based on an undiscounted AWP, "[t]he actual acquisition cost of individual pharmacies has no bearing upon the payment Medi-Cal makes." *Id*. However, the report also noted that the margins providers realized between their reimbursement payments and their actual costs to acquire drugs served to offset inadequate dispensing fees. *Id*.

In 1985, the Health Care Financing Administration ("HCFA"), the federal agency that administers the Medicaid program, conducted a survey of pharmacy acquisition costs in the state of California and prepared a report detailing its findings.[2] SOF at ¶ 24. The report, which was provided to officials at the California Department of Health Services ("DHS"), the California agency that administers the Medi-Cal program, found that California pharmacists acquired drugs generally at an average of 16.63 percent below AWP and acquired generic drugs specifically at an average of 22.14 percent below AWP. *Id*. In a February 4, 1986 letter to HCFA

[2] In 2000, HCFA changed its name to the Centers for Medicare and Medicaid Services ("CMS"). When the agency is referenced in this brief in a context prior to 2000, it will be referred to as HCFA. When it is referenced in a context from 2000 to the present, it will be referred to as CMS.

acknowledging receipt of a draft of the report, John Rodriguez, then Deputy Director for Medical Care Services at DHS, expressed concern that the report advocated a downward adjustment to Medi-Cal's Estimated Acquisition Cost ("EAC") calculation, which at the time was an undiscounted AWP. SOF at ¶ 25. In particular, Mr. Rodriguez noted that "successfully 'tightening up' our EAC program will concomitantly result in enormous pressure for California's Medi-Cal program to upgrade the dispensing fee. … If, in fact, costs are only shifted, is a change in federal regulations or more aggressive enforcement of existing EAC regulations really cost effective?" *Id*.

When California adopted HCFA's 1987 FUL regulations, its statement of reasons compared reimbursements, which were based on undiscounted AWPs at the time, to provider costs for a brand version and a generic version of the same drug. SOF at ¶ 26. To determine the provider's costs, California relied on prices from wholesalers' catalogs. *Id*. The final statement of reasons concluded that the FUL regulations benefit both Medi-Cal, by encouraging providers to dispense lower cost generic drugs, and the provider, who typically realizes a larger profit margin between her cost for a generic drug and the published AWP than for a brand name drug. *Id*.

In September of 1989, DHS revised its EAC formula to AWP minus five percent. SOF at ¶ 28. This change was approved by HCFA, as were all changes to Medi-Cal's reimbursement rates. SOF at ¶ 5. In 1991, the California Auditor General noted this change in a report, stating it had been made in response to guidance from HCFA that directed state Medicaid agencies that AWP must be discounted if it is used to calculate EAC. *Id*. The Auditor's report also cited a 1989 report prepared by the Office of Inspector General for the United States Department of Health and Human Services ("HHS-OIG") that compared published AWPs to prices charged by

national drug wholesalers. *Id.* The report found that the average discount off of AWP for generic drugs was 18.2 percent, and that prices for generic drugs in one wholesaler's catalog were on average more than 30 percent below AWP. *Id.* The 1989 report also quoted a wholesaler representative stating "AWP is a meaningless figure" and a Pennsylvania Medicaid official saying that AWP "… just doesn't mean anything. It has no connection to what pharmacies really purchase the drugs for." *Id.*

In 1994 and 1995, the HHS-OIG conducted a survey of Medi-Cal providers' acquisition costs for drugs, with help from DHS employees. SOF at ¶¶ 29-31. The HHS-OIG published the results of the survey in 1996, in a report entitled "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the California Department of Health Services" (A-06-95-00062) (the "1996 HHS-OIG Report"). SOF at ¶ 32. The 1996 HHS-OIG Report found that, on average, Medi-Cal pharmacists' invoice prices for generic drugs were 41.4 percent below AWP. *Id.* In his response to the 1996 HHS-OIG Report, John Rodriguez noted that the report affirmed DHS's position that California's pharmacy reimbursement payments did not reflect pharmacists' actual costs for drugs. *Id.*

Current and former Medi-Cal officials testified that they understood from as early as 1985, and certainly by the mid to late 1990s, that AWPs did not reflect prices charged in the marketplace, in particular for generic drugs, and that Medi-Cal's drug reimbursement payments were higher than providers' acquisition costs. SOF at ¶¶ 37- 40.

In 1996, just a few months after the publication of 1996 HHS-OIG Report finding that Medi-Cal providers could purchase generic drugs at an average of 41.4 percent below AWP, the California legislature considered abandoning the AWP minus five percent methodology in favor of a methodology that would pay the lesser of AWP minus ten percent or Wholesale Acquisition

Cost ("WAC") plus seven percent, on a drug-by-drug basis. SOF at ¶ 33. In its analysis of this proposal, DHS noted that the reductions would bring reimbursement payments closer to pharmacists' actual acquisition costs, but warned that the change could drive providers from the program and would impair DHS's working relationship with California Pharmacists Association ("CPhA") and undermine efforts to resolve other inequities in the drug reimbursement system, including inadequate dispensing fees. *Id.* This proposal was ultimately not adopted. SOF at ¶¶ 19-21.

In 1997, the Ninth Circuit enjoined DHS from reducing the rates it reimburses hospitals for providing outpatient services to Medi-Cal beneficiaries. *Orthopaedic Hosp. v. Belshe*, 103 F.3d 1491, 1500 (9th Cir. 1997), *cert. denied*, 522 U.S. 1044 (1998). The Ninth Circuit ruled that federal law requires DHS to perform studies to ensure that any revisions to Medi-Cal reimbursement rates are consistent with the goals of efficiency, economy, quality service, and access. The Ninth Circuit affirmed this holding earlier this year when it enjoined a ten percent reduction in all Medi-Cal reimbursement payments, including payments to pharmacies. *See Indep. Living Ctr. of S. Cal., Inc. v. Maxwell-Jolly*, 572 F.3d 644 (9th Cir. 2009).

In 1999, analyzing another proposal to move from AWP minus five percent to AWP minus ten percent or WAC plus seven percent, Vic Walker, a Pharmacy Consultant with DHS, noted that providers and beneficiary advocacy groups had aggressively opposed such changes in the past, and advised that the proposal should be implemented by the legislature, rather than through administrative rule making, so that it could "sustain legal challenges." SOF at ¶ 35. Again, this proposal was not adopted. SOF at ¶¶ 19-21.

In 2000, DHS formally opposed a proposed reduction to AWP minus 15 percent "without first taking steps to determine an appropriate rate of reimbursement. Federal law requires that

the state assure that '…payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers…' [Social Security Act Section 1902(a)(30)(A)] which can best be demonstrated through performance of a proper rate study." SOF at ¶ 36. DHS argued that, without the benefit of the rate study that was required by the Ninth Circuit in *Orthopaedic Hospital*, "Medi-Cal may suffer a serious patient access problem as providers disenroll from Medi-Cal rather than accept the reduced payment." *Id*. This proposal, like the others, was not ultimately adopted. SOF at ¶¶ 19-21.

II. THE ORIGINAL QUI TAM COMPLAINT

In July 1998, the Relator initiated this action by filing a *qui tam* complaint under seal in California state court, naming as defendants 23 drug manufacturers, including Dey, Inc. SOF at ¶ 60. Relator's *qui tam* complaint described how published prices for drugs, especially generic drugs, exceeded providers' acquisition costs and resulted in payments by Medi-Cal that substantially exceeded costs. SOF at ¶ 61. The *qui tam* complaint also compared Medi-Cal payments to prices available to Relator for four of the five Dey Subject Drugs. *Id*. These comparisons reveal large "spreads" on these drugs, for some more than 500 percent. *Id*. Although the *qui tam* complaint was filed under seal, Relator was required by law to provide copies to the California Attorney General's Office. Cal. Gov't Code § 12652 (c)(1) and (c)(2).

III. THE MYERS AND STAUFFER REPORTS

In 1999, California commissioned nationally renowned consultants Myers and Stauffer to conduct a survey of California pharmacists' costs for acquiring drugs, as well as their costs associated with dispensing drugs. SOF at ¶ 41. In August of 2002, Myers and Stauffer issued two reports detailing its findings. SOF at ¶ 42.

The first report, entitled "A Survey of Acquisition Costs of Pharmaceuticals in the State of California," examined pharmacists' actual acquisition costs for the top 2,000 drugs as

measured by Medi-Cal expenditures. SOF at ¶ 43. The report found that pharmacists could acquire single-source drugs for an average of 82.8 percent of AWP, multi-source (*i.e.* generic) drugs without a Federal Upper Limit ("FUL") for an average of 56.6 percent of AWP, and multi-source drugs with a FUL for an average of 12.7 percent of AWP and 38.7 percent of the FUL. SOF at ¶ 44.[3] The report included lists comparing published AWPs to average actual acquisition costs on an individual unit basis for the top 200 multi-source drugs without FULs and the top 200 multi-source drugs with FULs. SOF at ¶ 45. These lists contain no fewer than 78 NDCs for the Subject Drugs. *Id*. Not surprisingly, the report found that California's ingredient reimbursement rate of AWP minus five percent paid providers considerably more than their actual acquisition cost for drugs, and that providers typically realized a $10 margin over their actual acquisition costs per reimbursement. SOF at ¶ 46. However, the report cautioned that comparisons of ingredient reimbursement payments and ingredient costs could not be considered in isolation, and should be evaluated in conjunction with dispensing fee payments and providers' costs for dispensing drugs. *Id*.

The second report, entitled "Study of Medi-Cal Pharmacy Reimbursement," examined Medi-Cal pharmacy providers' costs to dispense drugs. SOF at ¶ 47. The report found that a Medi-Cal pharmacy provider's average cost of dispensing drug, weighted by volume, was $8.69. *Id*. Even excluding intravenous and compounded drugs, the average cost of dispensing a prescription was $7.21, more than $3.00 above the $4.05 dispensing fee then paid by California. *Id*. Thus, while California's ingredient reimbursement payments may have been more than providers' costs for drugs, its dispensing fee payments were considerably *below* providers' costs to dispense drugs.

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[3] Under California's approach to calculating so-called "spreads," a drug acquired at 12.7 percent of AWP would have a "spread" of 687 percent.

To demonstrate the importance of considering ingredient cost reimbursement in conjunction with the dispensing fee, the 2002 dispensing cost report included an analysis of overall cost to the pharmacist per prescription (including both the pharmacist's cost to acquire the drug *and* the pharmacist's cost to dispense the drug), the average reimbursement payment by Medi-Cal per prescription (including both the ingredient cost reimbursement *and* the dispensing fee), and the average margin for various categories of drugs per prescription:

	Average cost	**Average Payment**	**Average Spread (Dollars)**	**Average Spread (Percent)**
Brand drugs	$120.36	$133.14	$12.78	9.6%
Generic drugs without FULs	$28.87	$38.34	$9.47	24.7%
Generic drugs with FULs	$10.46	$11.73	$1.27	10.9%

SOF at ¶ 48.

Comparing the combined figures for generics with those for brands is particularly revealing. While the percentage margin or "spread" a provider realizes on reimbursement for a non-FULed generic is two and a half times larger than the percentage margin for a brand drug, the actual dollar amount of the margin is three dollars less. Moreover, the average total payment by Medi-Cal for a non-FULed generic is almost $100 less than total payment for a brand drug. The numbers are even more striking for FULed generic drugs, which, in Plaintiff's parlance, had average "spreads" of almost 700 percent. While the percentage margins for brand drugs and FULed generic drugs are roughly the same, the $12.78 average margin a provider receives on brand drugs is ten times the $1.27 average margin for a FULed generic. Likewise, Medi-Cal's $133.14 average payment for a brand drug is over $120 more than Medi-Cal's $11.73 average payment for a FULed generic.

As these figures demonstrate, the so-called "mega-spreads" on generic drugs, including those at issue in this action, do not cause "inflated" or "excessive" reimbursement payments to

Medi-Cal providers who dispensed these drugs. Quite the opposite: the total payments that Medi-Cal providers received were relatively modest compared to providers' costs, due to Medi-Cal's inadequate $4.05 dispensing fee. Indeed, were it not for the "spreads" for some drugs, particularly generic drugs with FULs, Medi-Cal providers would lose money dispensing drugs to beneficiaries. Given the Myers and Stauffer finding that the average cost of dispensing was $7.21, a Medi-Cal provider's average ingredient cost for a FULed generic drug would be $3.25 (the provider's total average cost of $10.46 minus the provider's $7.21 cost of dispensing). If Medi-Cal's ingredient cost reimbursement payment were equal to the provider's actual acquisition cost, the resulting reimbursement payment to the provider would be $7.30 ($3.25 for the ingredient cost of the drug plus Medi-Cal's $4.05 dispensing fee). Given the provider's total average cost of $10.46 for generic drugs with FULs, reimbursement at $7.30 would result in an average net loss of $3.16, or 40 percent, for each FULed generic prescription.

IV. THE SECOND AMENDED QUI TAM COMPLAINT

Around the same time that Myers and Stauffer published its reports, Relator amended its *qui tam* complaint to add several more drug manufacturers, including Mylan and Sandoz. SOF at ¶ 62. Like the previous version of the *qui tam* complaint filed four years earlier, the amended complaint alleged how California's reliance on published AWPs purportedly resulted in reimbursement payments that dramatically exceeded providers' acquisition costs for generic drugs. SOF at ¶ 63. Moreover, like the prior complaint, the amended complaint included comparisons of Medi-Cal payments and providers' actual costs for 283 NDCs for the Mylan Subject Drugs and 17 NDCs for the Sandoz Subject Drugs. *Id*. These comparisons reveal large "spreads" on these drugs, many of them more than 1000 percent. *Id*. Despite the wealth of information California already had concerning the prices actually paid for generic drugs,

California waited three more years, until August of 2005, to intervene and begin pursuing these claims. SOF at ¶ 64.

V. CALIFORNIA'S CHANGES TO ITS REIMBURSEMENT METHODOLOGY FROM 2002 TO THE PRESENT

With the release of the 2002 Myers and Stauffer reports, California now had the "proper rate study" required by *Orthopaedic Hospital* to set a reimbursement rate that would be "consistent with efficiency, economy, and quality of care and [] sufficient to enlist enough providers." 42 U.S.C. § 1396a(a)(30)(A). Indeed, California proceeded to do just that, first in December of 2002, and again in September of 2004. SOF at ¶¶ 51-54.

In December of 2002, a law passed by the California legislature reduced Medi-Cal's ingredient reimbursement rate from AWP minus five percent to AWP minus ten percent, and left the dispensing fee unchanged at $4.05. SOF at ¶¶ 52-53. In an enrolled bill report, DHS noted that, based on studies finding that brand drugs were available at AWP minus 15 to 17 percent and generics were available at AWP minus 40 to 50 percent, the bill originally called for reimbursing for brand drugs at AWP minus 10 percent and generic drugs at AWP minus 40 percent. SOF at ¶ 52. However, DHS went on to note that providers' costs for dispensing drugs were significantly higher than California's $4.05 dispensing fee, which would not be changed by the legislation, and that the providers relied on the margins they received from ingredient cost reimbursements to make up for the inadequate dispensing fee. *Id*. In response to contentions from the CPhA that many providers would be unable to continue providing services if the proposed rate cut were implemented, DHS noted that the proposed switch to AWP minus 40 percent for generics was dropped, and the AWP minus ten percent rate was adopted for all drugs. *Id*. In other words, California struck a compromise between the competing interests of economy and access to care, as required by 42 U.S.C. 1396a(a)(30)(A), and knowingly and deliberately

chose to pay large percentage spreads (spreads of 100 percent on average) on generic drugs, relying on the relatively small dollar "spreads" to make up for shortfalls in its dispensing fee payment. *Id*. As with all changes to California's Medicaid reimbursement methodologies, this change was approved by the federal government. SOF at ¶ 5.

California changed its reimbursement methodology again in September of 2004, lowering EAC to AWP minus 17 percent and raising the dispensing fee to $7.25. SOF at ¶ 54. DHS initially proposed a reduction of ingredient reimbursement to AWP minus 20 percent (which was still significantly higher than the acquisition costs indicated by Myers and Stauffer), but concerns over access to drugs, particularly for long-term care facilities, caused it to raise the rate to AWP minus 17 percent. SOF at ¶ 55. While there was considerable discussion within DHS prior to the implementation of the change as to what the appropriate reimbursement rate would be, those discussions focused on the balance between achieving overall savings for the program and ensuring sufficient enrollment in the program. SOF at ¶¶ 55-58. DHS understood that the AWP minus 17 percent EAC would result in reimbursement payments for generic drugs that were significantly higher than providers' acquisition costs, and specifically pointed this out to the legislature. SOF at ¶ 58. Indeed, DHS officials knew that the proposed methodology would result in margins to pharmacists of more than 180 percent on average for generic drug reimbursement payments. SOF at ¶ 55. DHS nonetheless advocated the AWP minus 17 percent change because the balance of cost-savings and access to quality care this change ensured outweighed the small dollar-amount margins providers would receive for generic drugs. SOF at ¶¶ 55-58. This change too, was approved by the federal government. SOF at ¶ 5.

Indeed, even today, four years after intervening in this action, California knowingly pays manufacturers "spreads" on drugs and in fact relies on the "spreads" to compensate for

inadequate dispensing fees. In January of this year, a group of providers commenced an action in the United States District Court for the Central District of California to enjoin the California Department of Health and Human Services from implementing an across-the-board, five percent reduction in pharmacy reimbursement. SOF at ¶¶ 65-66. California's opposition to the providers' motion for a preliminary injunction included an affidavit executed by Kevin Gorospe, the current Chief of the Pharmacy Policy Unit at DHS. SOF at ¶ 67. In his affidavit, Mr. Gorospe noted that California's dispensing fee of $7.25 was significantly below DHS's own estimate of the average dispensing cost per prescription of $11.59. *Id*. However, Mr. Gorospe went on to state that providers' costs were covered by the "significant profit on Medi-Cal reimbursement for the drug itself." *Id*. In any event, the Central District of California enjoined this rate adjustment as well.

ARGUMENT

I. LEGAL STANDARDS

A. Summary Judgment

Summary judgment should be granted where there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *J. Geils Band Employee Benefit Plan v. Smith Barney Shearson, Inc.*, 76 F.3d 1245, 1250 (1st Cir. 1996). To succeed in a motion for summary judgment, the moving party must show that "there is an absence of evidence to support the nonmoving party's case." *Id*. at 1251. (citing *FDIC v. Municipality of Ponce*, 904 F.2d 740, 742 (1st Cir. 1990)). To defeat summary judgment, the non-movant must come forward with more than "conclusory allegations, improbable inferences, and unsupported speculation…[or] brash conjecture coupled with earnest hope that something concrete will materialize." *Id*.

B. The California False Claims Act

California brings this action under the California False Claims Act, Cal. Gov't Code § 12650, *et seq*. ("CFCA"), which, in relevant part, imposes liability on any person who:

> (1) Knowingly presents or causes to be presented to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval.
>
> (2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision.

Cal. Gov't Code § 12651 (a)(1) and (a)(2). "[T]he [California] False Claims Act is patterned largely on its federal counterpart and therefore federal decisions are persuasive on the meaning of the Act…" *Am. Contract Servs. v. Allied Mold & Die, Inc.*, 114 Cal. Rptr. 2d 773, 777 (Cal. Ct. App. 2001) (internal citations omitted).

II. AS A MATTER OF LAW, CALIFORNIA CANNOT ESTABLISH THAT DEFENDANTS CAUSED ANY DAMAGES FROM 1997 TO THE PRESENT

California cannot establish that Defendants' price reporting practices caused it any damage from 1997 to the present. Since January of 1997, controlling case law in the Ninth Circuit has required California to set its Medicaid reimbursement payment rates at levels consistent with the four factors set forth in 42 U.S.C. § 1396a(a)(30)(A): efficiency, economy, quality of care, and access. *See Orthopaedic Hosp.*, 103 F.3d at 1496. Since that time, California maintained its pharmacy reimbursement rates at levels that would ensure these goals, knowing full well that they resulted in payments that were higher than providers' acquisition costs. Thus, the alleged "overpayments" that California seeks to recover as damages in this action were not "overpayments" at all, but were rather the payments that California, after careful study and extensive surveys, deemed sufficient and necessary to ensure that the pharmacy benefit

under the Medi-Cal program was administered efficiently and economically, and to ensure that Medi-Cal beneficiaries had adequate access to quality care.

A. Damages under the CFCA

The CFCA only permits recovery of damages that were caused "because of the act of [Defendants]." *See* Cal. Gov't Code § 12651. The restrictive "because of" language limits California's recovery of damages to injuries that were proximately caused by the alleged false statements or false claims. *See Fassberg Constr. Co. v. Hous. Auth. of the City of Los Angeles*, 60 Cal. Rptr. 3d 375, 401-02 (Cal. Ct. App. 2007) (applying proximate cause standard to claims under the CFCA). Under this analysis, a defendant will only be liable for damages that were proximately caused by his conduct, and will not be liable for injuries that were the result of an intervening cause. *See United States ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F. 3d 402, 416 (3d Cir. 1999) (applying intervening cause analysis to FCA claim).

B. The Ninth Circuit's Holding in *Orthopaedic Hospital*

Since 1997, Medi-Cal has been required by law to set its reimbursement rates at a level sufficient to ensure economy, efficiency, quality of care and access. Medi-Cal has also been required to conduct studies to ensure that its reimbursement payments are sufficient to permit access to quality medical services. *See Orthopaedic Hosp. v. Belshe*, 103 F.3d at 1496. In *Orthopaedic Hospital*, a group of hospital providers sought review of DHS's reduction in its reimbursement rates to hospitals on the grounds that DHS had implemented the reduction without considering that hospitals incurred greater costs than other types of providers when providing outpatient services. *Id*. at 1494-95. The hospital providers contended that the reduction in rates violated 42 U.S.C. 1396a(a)(30)(A), which provides in relevant part that Medicaid programs must:

> provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan … as may be necessary to … assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area…

42 U.S.C. 1396a(a)(30)(A).

The Ninth Circuit reversed the district court's grant of summary judgment for Medi-Cal, holding that 42 U.S.C. § 1396a(a)(30)(A)'s requirement that reimbursement payments be "consistent with efficiency, economy, and quality of care" required Medi-Cal to set its reimbursement rates at levels that would provide payments consistent with those factors and to conduct studies to ensure that its payments satisfy these factors. *Id*. at 1500. The Ninth Circuit rejected California's argument that section 1396a(a)(30)(A) was satisfied because the reduction in rates did not in fact impact provider participation in the program.

> De facto access, produced by factors totally unrelated to reimbursement levels, does not satisfy the requirement of 1396a(a)(30)(A) that payments must be sufficient to enlist enough providers. … Hospitals have a legal obligation to provide those services regardless of the level of Medi-Cal reimbursement rates. … A hospital's only option to avoid accepting insufficient Medicaid reimbursements is to close their emergency departments or stop accepting federal funds through Medicare.

Id. at 1497. The Court also rejected California's argument that the rates it established were sufficient to cover costs of outpatient procedures by non-hospital providers on the grounds the payments would impair Medi-Cal beneficiaries' access to care:

> [Medi-Cal] contends that it shouldn't have to compensate hospitals for their costs because emergency rooms are overused and are often used for non-urgent conditions. True as this may be, emergency rooms are overused precisely because they are the only accessible providers of primary care for many people, particularly Medicaid recipients. [Medi-Cal] cannot ensure access by relying on regulations requiring hospitals to treat patients in the emergency room, and then refuse to pay the cost of such treatment because

> theoretically it could have been provided more efficiently elsewhere. Nowhere does it appear that [Medi-Cal] inquired whether Medi-Cal beneficiaries had adequate access to outpatient services in non-hospital settings.

Id. at 1499-1500.

The Ninth Circuit recently affirmed its holding in *Orthopaedic Hospital* in the case *Maxwell-Jolly*. *See* 572 F.3d 644. In *Maxwell-Jolly*, the Court upheld an injunction against the implementation of an across-the-board ten percent reduction to Medi-Cal reimbursement payments, including payments for pharmacy reimbursement, because the reduction was implemented without consideration of its impact on access to care. *Id*. at 648. Just as in *Orthopaedic Hospital*, the Ninth Circuit held that, by failing to study the impact of the reduction on efficiency, economy, quality, and access, both DHS and the California legislature violated 42 U.S.C. § 1396a(a)(30)(A). *Id*. at 652. In its ruling, the Ninth Circuit also rejected DHS's argument that the state's budgetary woes justified the rate cut, finding that "any such harm was outweighed by the hardships likely to be suffered by Medi-Cal beneficiaries, who would be forced to go without medical care." *Id*. at 657. As the Court put it:

> State budgetary considerations do not therefore, in social welfare cases, constitute a critical public interest that would be injured in the grant of preliminary relief. In contrast, there is a robust public interest in safeguarding access to health care for those eligible for Medicaid, whom Congress has recognized as the most needy in the country.

Id. at 659.

C. California's Reimbursement Payments for the Drugs at Issue Were Consistent With Efficiency, Economy, Quality of Care And Access and Did Not Cause California Any Injury

Faced with the judicial mandate from the Ninth Circuit, California continued to continued to reimburse at the same level for a number of years, apparently concluding that its methodology balanced the various factors set forth in 42 U.S.C. § 1396a(a)(30)(A). The evidence in the record

demonstrates, therefore, that the alleged "overpayments" that form the basis of California's damages claims were the direct and proximate result of California's deliberate execution of its legal obligation to pay reimbursement rates consistent with efficiency, economy, quality of care, and access, and not by any fraudulent conduct on the part of Defendants.

The record demonstrates that, starting in 1977 and up to the time the Ninth Circuit issued its decision in *Orthopaedic Hospital*, California was well aware that Medi-Cal's AWP minus five percent reimbursement methodology was paying providers considerably more than their actual acquisition costs for generic drugs. SOF ¶ 23. Indeed, with the publication of the 1996 HHS-OIG Report California was aware that providers could obtain generic drugs at an average discount of more than 40 below AWP. SOF at ¶ 32. Despite this knowledge, California ultimately rejected several proposals in the late 1990s and early 2000s to reduce pharmacy reimbursement, first with proposals to move from AWP minus five percent to AWP minus ten percent or WAC plus seven percent in the late 1990s, and later in 2000 to move to AWP minus 15 percent. SOF at ¶¶ 33-36. The evidence in the record demonstrates that California's concerns about the negative impacts on access to care were central in its decisions to reject these proposals, and that concerns about approximating providers' actual acquisition costs were secondary, at best. For instance, when proposals to move to AWP minus 10 percent or WAC plus 7 percent were made, DHS recognized that such a change would face legal challenges and that potential savings could well be outweighed by significant access problems. SOF at ¶¶ 33, 35. Indeed, in 2000, DHS formally opposed the proposal to move to AWP minus 15 percent, on the grounds that a proper study had not been performed to assess its impact on providers' continued participation in the program. SOF at ¶ 36.

Moreover, as discussed below, when California did receive a formal "rate study," it still chose to adopt reimbursement rates it knew would pay providers more than their acquisition costs for the drugs, because those rates were most consistent with the required goals of efficiency, economy, quality of care, and access. When California adopted AWP minus 10 percent in 2002 and AWP minus 17 percent in 2004, it knew that it would be paying providers large "spreads" for generic drugs. SOF at ¶¶ 54-59. Indeed, when DHS officials were considering the changes that were ultimately adopted in 2004, they expressly acknowledged that Medi-Cal would end up paying "spreads" of 180 percent on average for generic drugs. SOF at ¶ 55. Paying what California now rhetorically characterizes as "mega-spreads" (based on percentage margins, not dollar margins) for dispensing generic drugs is entirely consistent with the goals of efficiency, economy and access to quality care.

First, the Myers and Stauffer report demonstrated that Medi-Cal's $4.05 dispensing fee in effect during almost all of the relevant time period was wholly inadequate to compensate providers for their cost of dispensing drugs, and that providers relied on margins from ingredient cost reimbursements to cover their dispensing costs. SOF at ¶¶ 46-48. Thus, the alleged "spreads" that California paid were deliberately intended to compensate providers for the inadequate dispensing fee. California acknowledged as much when it rejected the possible move to AWP minus 40 percent for generics in 2002. *Id*. Even today, Medi-Cal officials acknowledge that the "spreads" Medi-Cal pays on the ingredient portion of reimbursement are necessary to make up for the inadequate dispensing fees California pays. SOF at ¶ 67. Second, while the percentage margins Medi-Cal pays for generic drugs may appear high, the actual dollar amounts of generic margins are low, generally lower than the dollar amounts of the brand margins. Since payments for generics constitute a small percentage of Medi-Cal's total drug reimbursement

payments, these small dollar margin payments have relatively little impact on Medi-Cal's overall expenditures, as Medi-Cal officials themselves have acknowledged. SOF at ¶ 55. At the same time, as California recognized when it adopted the FUL regulations in 1987, the higher profit margins on generics create an incentive for providers to dispense generics instead of brands. SOF at ¶ 26. The net result is lower overall expenditures by Medi-Cal, coupled with profit levels sufficient to ensure continued participation by Medi-Cal providers.

D. Defendants Should Not Be Liable for Payments Medi-Cal Made That Were Consistent With Its Obligations Under Federal Law

Defendants cannot be liable for payments California made as a result of its own informed policy decision which were themselves driven by a federal legislative and judicial mandate. As California's own policy deliberations demonstrate, it knowingly paid providers more than their acquisition costs for drugs because those payments were necessary to ensure that providers participated in the program. California cannot now claim that those payments caused it injury for which Defendants should be liable.

The Supreme Court of Alabama recently rejected a similar attempt by the State of Alabama to hold drug manufacturers liable for drug reimbursement payments that Alabama understood were higher than providers' actual costs. *See AstraZeneca L.P. v. State*, No. 1071439, 2009 WL 3335904 (Ala. Oct. 16, 2009). Although the Alabama case turned on the issue of reasonable reliance under a common law fraud claim, the Alabama Supreme Court's rationale is equally applicable here:

> Because there is no evidence indicating or contention that [Alabama] intends to discontinue its Medicaid program, it must not have intended to discount the actual AWP by 10.2%. … Thus, the State's argument that it believed the published AWPs to represent actual AWPs is simply untenable. On the contrary, it is clear beyond cavil that the reimbursement methodology adopted by the AMA is the product of a conscious and deliberate policy decision, which seeks to balance (i) the amount [Alabama] reimburse[s]

> pharmacies that dispense drugs to Medicaid patients, and (ii) the requirement – established by federal law – to set reimbursement sufficiently high to ensure participation in the Medicaid program by retail pharmacies.
>
> Thus, we agree with AstraZeneca when it contends that this litigation is essentially an attempt to use tort law to redefine [Alabama's] Medicaid reimbursement obligations.

Id. at *16 (internal citations and quotations omitted).[4] The same is true here. California deliberately paid providers the amounts it determined were the most consistent with efficiency, economy, and access to quality care as required by federal law. It cannot now use the CFCA to retroactively pass the costs of fulfilling its federal obligations along to Defendants by relabeling those payments as "overpayments." Accordingly, California's damages from January 1997 to the present should be reduced to zero.

III. AS A MATTER OF LAW, CALIFORNIA CANNOT ESTABLISH ITS CFCA CLAIMS AFTER AUGUST OF 2002

While California cannot recover any damages from Defendants after January of 1997, California's claims are barred in their entirety as a matter of law at least as of August 2002. There is no question of fact that, following California's receipt of the Myers and Stauffer reports and the filing of the first amended *qui tam* complaint in August of 2002, California was fully aware of so-called "mega-spreads" for many of the Subject Drugs on an NDC-specific level, fully expected to be paying spreads on average of 200 percent for generic drugs, and intentionally adopted reimbursement methodologies that would pay these so-called "mega-spreads" for its own policy reasons, which included ensuring access. California's expectations concerning generic AWPs refute the elements of falsity and *scienter* under its CFCA claims after August of 2002.

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[4] Defendants note that a certificate of judgment has not yet been entered in that action, and that an application for rehearing is pending before the Alabama Supreme Court.

A. California's Knowledge Negates Falsity and *Scienter* Under the CFCA

In an action under the CFCA, the government's "knowledge [of a fraud] effectively negates the fraud or falsity required by the [CFCA]." *Am. Contract Servs.*, 114 Cal. Rptr. 2d at 780; *see also United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 682 n.8 (5th Cir. 2003) ("Inevitably, the extent of the government's knowledge is also bound up with whether the claim itself was false"). Likewise, "government knowledge" vitiates the requisite *scienter* under the CFCA: "there cannot be a knowing presentation of a false claim for payment where the government is fully aware of the facts surrounding the claim and approves it." *United States v. Shasta Services Inc.*, 440 F. Supp. 2d 1108, 1113 (E.D. Cal. 2006). Thus, if California knows of the allegedly "false" nature of Defendants' published AWPs but continues to use them to pay reimbursement claims, the claims at issue could not have been "false" nor could Defendants have knowingly caused the submission of "false" claims.

The case *United States ex rel. Englund v. Los Angeles County*, No. CIV. S-04-282 LKK/JFM, 2006 WL 3097941 (E.D. Cal. Oct. 31, 2006) is particularly instructive. In that case, the defendant Los Angeles County, which operated hospitals that serviced Medicaid beneficiaries, engaged in a complex scheme of intergovernmental funds transfers to receive federal payments for providing services to Medicaid beneficiaries that were greater than what it would otherwise be entitled to receive. *Id*. at *8. The court granted summary judgment in favor of the defendant on the grounds that CMS was well aware of the practice of using intergovernmental funds transfers to obtain inflated federal funding. *Id*. at *13. As the court held, "the Federal government was fully aware of the County's practices and thus the County did not act with the requisite intent to deceive." *Id*. at *15. Similarly, California "was fully aware of [Defendants'] practices and thus the [Defendants] did not act with the requisite intent to deceive." *Id*.

B. The 2002 Myers and Stauffer Report Apprised California Of Spreads for Many of the Subject Drugs

The evidence in the record clearly establishes that, following California's receipt of the Myers and Stauffer reports in August of 2002, Defendants could not have caused the submission of false claims as a matter of law. The Myers and Stauffer reports – the "proper rate studies" Medi-Cal officials felt were needed to make appropriate adjustments to reimbursement payments – clearly established for California that generic drugs like the Subject Drugs could be acquired, on average, at a fraction of published AWPs. SOF at ¶ 44. Specifically, the report found that generic drugs without FULs could be purchased for about half of the published AWPs. *Id*. For generic drugs with FULs, the report found that providers paid, on average, around 13 percent of the published AWP and 38 percent of the applicable FUL. *Id*. In other words, even when Medi-Cal reimbursed based on a FUL, it was paying an average "spread" of 172 percent.

If that were not enough, the reports compared AWPs to averages of actual acquisition costs for 78 of the Subject Drugs. SOF at ¶ 45. The drugs were identified by NDC, so that the manufacturers of the drugs were readily identifiable. *Id*. Examples of each of the Defendants' drugs are listed below:

Drug/NDC	Average actual acquisition cost per unit`	Published AWP per unit	Spread
Mylan's cimetidine 00378037205	$0.05	$1.61	3055%
Mylan's diphenoxylate/atropine 00378041510	$0.09	$0.48	419%
Dey's ipratropium 49502068503	$0.21	$0.71	238%
Dey's albuterol sulfate 49502069703	$0.07	$0.40	471%
Sandoz' Amiodarone HCL 00781120360	$0.57	$3.13	447%
Sandoz' Atenolol 00781150701	$0.03	$1.04	3836%

Id.

These reports were made available to the California legislature and played a key role in DHS's recommendations regarding changes to the reimbursement methodology after August of 2002. SOF at ¶ 49.

C. The Relator's First Amended Qui Tam Complaint Apprised California of Spreads for Almost All of the Subject Drugs

Moreover, by the same date, Relator had presented to California the large spreads between Medi-Cal payments and providers' acquisition costs for almost all of the Subject Drugs on an NDC specific level through the filing of its *qui tam* complaints. For Dey, California had this information at least since it received the original *qui tam* complaint in July 1998. For Mylan and Sandoz, Relator provided this information to California in August 2002, when Relator filed its first amended *qui tam* complaint. The amended *qui tam* complaint consists almost exclusively of lists comparing published AWPs to Relator's actual costs. The prices listed in the *qui tam* complaints merely confirmed for California that large "spreads" existed for the Subject Drugs:

Drug	**Ven-A-Care's Cost (per package)**	**California's Payment (per package)**	**"Spread"**
Mylan's cimetidine 00378037205	$32.74	$765.68	2239%
Mylan's diphenoxylate/atropine 00378041510	$165.34	$422.75	156%
Dey's cromolyn 49502068902	$24.50	$39.90	62%
Dey's albuterol sulfate 49502069703	$8.50	$28.74	238%
Sandoz' alprazolam 00781107905	$7.04	$453.74	6345%
Sandoz' fluphenazine HCL 00781143901	$12.71	$109.01	378%

SOF at ¶¶ 61, 63.

D. California Deliberately Chose to Continue Paying "Mega-Spreads"

The extensive detail concerning drug pricing information provided to California in the Myers and Stauffer reports and the *qui tam* complaints is enough, on its own, to negate any showing of falsity or scienter by California, as they demonstrate that California was fully aware of the nature of the allegedly "false" claims at issue in this action. However, after the publication of the reports and the filing of the complaints, California adopted reimbursement methodologies that it understood would pay providers so-called "mega spreads" for generic drugs. As the evidence in the record demonstrates, California deliberately adopted these changes with full knowledge of the large spreads for its own policy reasons.

First, in the fall of 2002, California revised its reimbursement methodology from AWP minus five percent to AWP minus ten percent, but left the $4.05 dispensing fee unchanged. SOF at ¶¶ 51-53. In the enrolled bill report analyzing the proposal, DHS noted pricing studies, including the Myers and Stauffer report, finding that pharmacists could purchase generic drugs at an average of 40 to 50 percent below AWP. SOF at ¶ 52. However, DHS also noted that, because the proposed amendment would not raise the dispensing fee, a discount of more than ten percent for generics may not properly compensate providers for their services. *Id.* DHS approved the proposal, with full knowledge that Medi-Cal would be reimbursing pharmacies for generic drug ingredient costs at significantly more than the pharmacists paid to acquire generic drugs. *Id.*

California revised its reimbursement methodology again in 2004. SOF at ¶ 54. DHS initially proposed moving to a rate of AWP minus 20 percent, even though senior DHS officials expressed their understanding that this proposal would pay average spreads for generic drugs of approximately 180 percent. SOF at ¶ 55. Subsequently, DHS changed its proposal to AWP minus 17 percent, on the grounds that the cut would not significantly impact access to care, but

would still result in significant savings to the state fisc. SOF at ¶¶ 56-58. In its official endorsement of the revised methodology, DHS expressly acknowledged that it would be paying considerably more than the cost of generic drugs. SOF at ¶ 58.

In short, after August of 2002, California not only knew that the published AWPs for the specific drugs at issue dramatically exceeded providers' actual acquisition costs, but deliberately chose to continue to pay based on those prices, and continues to use them even today. As discussed *supra* at Point II, California adopted these rates so that it could ensure that its payments were consistent with economy, efficiency, and access to quality care as required by the Ninth Circuit. However, regardless of California's reasons, the facts are undisputed that California did pay these rates knowing the true nature of Defendants' AWPs and knowing full well the resulting reimbursements would be considerably higher than providers' actual acquisition costs for the Subject Drugs. Accordingly, there can be no falsity or scienter under the CFCA after August of 2002.

IV. CALIFORNIA CANNOT ESTABLISH CAUSATION OF DAMAGES FOR ANY CLAIM THAT WAS PAID ON THE BASIS OF A FUL

In its Complaint, California seeks to recover not only for claims for the Subject Drugs that were paid on the basis of AWP, but also for claims that were paid on the basis of the FUL, on the grounds that – had Defendants reported what California alleges were "true" AWPs for the Subject Drugs – then California's payments for the Subject Drugs would always have been below the applicable FULs. However, there is no evidence in the record that the prices that Defendants reported for the Subject Drugs would have had any discernable affect on the prices California ultimately paid for the FULed Subject Drugs. First, the evidence in the record demonstrates that, despite federal regulations dictating that FULs be set based on the lowest published price for a drug, the federal officials responsible for setting FULs rarely followed the

guidelines, and consequently, the prices Defendants reported for their drugs had little if any effect on the FULs that were ultimately set for those drugs. Second, even assuming that Defendants had reported so-called "true" prices, the evidence indicates that California would not have made lower reimbursement payments, as California's FUL-based reimbursement payments were barely enough to cover the providers' costs as it was, and lowering payments any further would likely have driven providers out of the program.

A. There Is No Causal Nexus Between Defendants' Reported Prices and FULs

In its decision on Defendants' motion to dismiss, this Court declined to dismiss claims for reimbursement payments for the Subject Drugs that were calculated based on the FUL because California alleged that the FULs are "formulaically" set at 150 percent of the lowest "wholesale acquisition cost (WAC), AWP, Direct Price or other published prices" among therapeutically equivalent drugs and that, therefore, "the complaint adequately alleges a nexus between the alleged fraudulent reporting of prices to the compendia and the establishment of the FUL." *In re Pharm. Indus. Average Wholesale Price Litig.* (*State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc.*), 478 F. Supp. 2d 164, 180 (D. Mass. 2007). However, the Court went on to dismiss claims based on California's State Maximum Allowable Ingredient Costs ("MAICs") because it concluded that California had failed to allege any causal link between the Defendants' price reporting and MAICs. *Id.*; *see also Fassberg Constr. Co.*, 60 Cal. Rptr. 3d at 401-02.

Subsequent discovery in this MDL has revealed that, just as there was no causal link between MAICs and Defendants' price reporting practices, there is likewise no causal connection between Defendants' reported prices and FULs for the Subject Drugs either as CMS did not follow the formula specified in the federal regulation when establishing FULs. Rather, the evidence indicates that the responsible CMS officials used the formula in the regulation as

merely a starting point, and would routinely establish FULs that bore no relation to 150 percent of the lowest published price of the therapeutically equivalent version, including FULs for Subject Drugs. SOF at ¶¶ 69-92.[5] There were no set guidelines CMS officials followed when setting FULs, and FUL determinations were made largely on an *ad hoc* basis. SOF at ¶¶ 69, 92. Indeed, the CMS officials who established the FULs testified that they routinely considered information that had nothing to do with the published prices for drugs, such as the AMPs manufacturers reported to CMS, MAC prices, the availability of the drug, and feedback from pharmacists and state Medicaid programs. SOF at ¶¶ 96-101. The CMS officials' overarching goal when establishing FULs was to strike the appropriate balance between cost-savings and access to care, not rigid adherence to the formula in the regulation. SOF at ¶¶ 93-95.

Since CMS did not adhere to the formula that formed the basis for this Court's determination to allow California to proceed with its FUL claims, California cannot establish a causal link between the prices Defendants reported for FULed Subject Drugs and the reimbursement payments it made based on FULs. Those claims must therefore be dismissed.

B. Payments Based on FULs Were Not "Overpayments"

California cannot save its claims for reimbursement payments based on FULs by arguing that, had Defendants reported "true" prices, California would have paid less for those claims, regardless of how CMS established FULs. There is no evidence in the record to support a claim that California would have ever paid pharmacists less than the FUL if Defendants had reported what California contends were the "true" prices. Rather, the evidence in the record demonstrates the opposite.

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[5] By way of example, sometimes CMS officials would consider prices for drugs that were not therapeutically equivalent (SOF at ¶¶ 84-85); sometimes it would use a price other than the most common package size (SOF at ¶ 86); sometimes it would obtain prices from manufacturers, rather than relying on publications (SOF at ¶ 87); and sometimes it would not implement a FUL when all the regulatory criteria were met (SOF at ¶ 92).

As the Myers and Stauffer reports noted, pharmacists barely broke even on Medi-Cal reimbursement payments for FULed drugs, due to the inadequate $4.05 dispensing fee that was in effect throughout most of the relevant time period. *See supra* at 9-10. Indeed, as discussed above, if Medi-Cal reimbursed providers at their actual costs to acquire a drug plus the $4.05 dispensing fee, the result would be an average net loss to the provider of 40 percent for every FUL reimbursement payment. *See supra* at 10. Given California's legal obligation under *Orthopaedic Hospital* to pay reimbursements that ensure access to quality care, coupled with its repeated concern that reductions in payments may drive providers from the Medi-Cal program, there is no basis in the record to support a contention that California would have willingly paid providers at a loss for the Subject Drugs that were reimbursed on the basis of FUL.

CONCLUSION

For the reasons set forth above, Defendants respectfully request that the Court grant this motion and enter judgment in favor of Defendants as to damages on California's CFCA claims after January of 1997, enter judgment in favor of Defendants on California's CFCA claims after August of 2002, enter judgment in favor of Defendants on all of California's CFCA claims arising from reimbursement claims paid on the basis of a FUL.

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on November 25, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Sarah L. Reid
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